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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Franz Freudenthal

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EXAMINER

OU, JING RUI

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/543,007	Applicant(s) FREUDENTHAL, FRANZ	
	Examiner JING RUI OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-50, 52-63 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) 74 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50, 52-63 and 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment and RCE filed on 11/08/2010. Claims 40-50, 52-63 and 65-75 are pending. Claims 40, 67, 71, and 74 are independent. Claims 74 and 75 are withdrawn from consideration. Claims 1-39, 51, and 64 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/08/2010 has been entered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "tissue and/or scrim and/or net structure" in claim 40 and the "thickness and concentration of material is different across the implantable device from distal portion to proximate portion" in claim 48 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 48-50 and 67-70 are objected to because of the following informalities: In line 4 of claim 48, the term "is" should be corrected to "are." In line 5 of claim 67, the phrase "implantable device being is transformable" is grammatically incorrect.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-50, 52-63, and 65-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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7. Claim 40 recites "a single intertwined, inter-coiled wire-like element having two ends having a tissue and/or scrim and/or net structure." It is unclear how the wire element having two ends can have a tissue and scrim and net structure. In addition, a tissue structure is being indefinite and unclear.

8. Claim 49 recites "a single wire-like element having different diameters." It is indefinite and unclear whether it is comparing between the diameters of the wire-like element and another object or the diameters of the wire-like element along different portions of its length.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 40-50, 52-59, 63, 65, and 66 rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Hyodoh et al (US Pub. No.: 2003/0149475) and Shaw et al (US Pat. No. 6,171,329).

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In regard to Claims 40-50, 52-59, 63, 65, and 66, Amplatz et al discloses a device comprising: a support structure (10) which has a primary shape which as a first length-to-width ratio along an axis in a primary shape (Fig. 5) and having secondary shape having second length-to-width ratio along said axis in a secondary shape (Fig. 7), two ends (ends at around 26 and 28), a proximal portion, and a distal portion (12 and 14); wherein said first length-to-width ratio is greater than said second length-to-width ratio; wherein the proximal portion/and or distal portion in the secondary shape is substantially flat in a disk shape (Fig. 7); and a delimited inner space (Fig. 5); wherein the inner space include an opening (Fig. 5, one of the openings between wires); wherein the proximal portion and the distal portion are placed flat and partially on top of one another (Fig. 2); wherein at least a partial area of the implantable device is folded (Fig. 5); wherein an eccentrically arranged central through-opening (the central channel space formed in the device) remains in the implantable device in the secondary shape of the support structure (Fig. 7); wherein an intermediate portion (16) having a reduced diameter compared to the proximal portion and distal portion (Fig. 5); wherein the primary shape is asymmetrically or irregularly configured (Fig. 5); wherein the material concentration inside the support structure is different from portion to portion (Fig. 5, the material concentration inside the support structure is different from the proximal end to the central portion); wherein the end of the proximal portion is completely close by provision of a plate element (30); the end of the distal portion or proximal portion has one or more loops which are interlaced in particular with a substantially uniform edge being formed (Fig. 7); wherein the support structure is designed as a two-part unit (12

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and 14) connected to one another to form one part; wherein individual parts of the support structure are designed uniformly (Fig. 7); the support structure of the implantable device in the primary shape is configured like a stent (a stent can have any shape); wherein one or more membranes are incorporated into the support structure (Col. 9, lines 55-58); wherein the membrane is formed by inweaving of at least one filament (a mesh is formed by inweaving of at least one filament); and wherein the wire-like element of the implantable device is made of nitinol (Col. 5, lines 48-60).

Amplatz et al does not appear to disclose that the support structure is formed from a single intertwined, inter-coiled wire-like element. However, Hyodoh et al discloses a support structure of an implantable device (10 or 700, Figs. 50A and 57B-D) formed from a single intertwined, inter-coiled wire-like element (Paras. [0146], [0152], and [0233]). Furthermore, Hyodoh et al teaches that the two ends of said wire-like element are both arranged at one end of said support structure. In addition, Shaw et al teaches a support structure of an implantable device formed from a single wire-like element (Shaw et al, Col. 13, lines 60-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the support structure of Amplatz et al to be formed from a single intertwined, inter-coiled wire-like element as taught by Hyodoh et al to enable the device to remain quite flexible in its compacted, inserted configuration (Shaw et al, Col. 13, lines 60-67) and by eliminating the use of two clamps since one clamp is needed.

Therefore, it would have been obvious to combine Hyodoh et al and Shaw et al with Amplatz et al to obtain the invention as specified in the instant claims.

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12. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Hyodoh et al (US Pub. No.: 2003/0149475) and Shaw et al (US Pat. No. 6,171,329) as applied above, and further in view of Gainor et al (US Pat. No.: 2002/0169475)

In regard to Claims 60-62, Amplatz et al discloses all the limitations of the claims but fails to disclose that the membrane is made of a material with a cross section differing from that of the wire like element and formed from a weave or scrim. However, Gainor et al teaches device comprising a membrane that is made of polyester with a cross section differing from that of a wire-like element and formed from a weave or scrim (Fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a membrane that is made of a polyester with a cross section differing from that of a wire-like element and formed from a weave or scrim to prevent large particles from go through the membrane.

13. Claims 67-69 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Shaw et al (US Pat. No.: 6,171,329).

In regard to Claims 67-69 and 71-73, Amplatz et al discloses all the limitations of the claims but fails to disclose a positioning system.

However, Shaw et al teaches a positioning system, comprising: an advancing element (62), a guide wire (42), and at least one retaining wire (96); wherein a retaining wire loop is formed (Fig. 12A); wherein said retaining wire is threaded through a loop at the end of the proximal portion of the implantable device and are connected to the guide

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wire. The number of retaining wire loops are merely an obvious designed choice and within one of ordinary skill in the art.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Amplatz et al and Shaw et al before him or her, to modify the system of Amplatz et al to include a positioning system comprising an advancing element, a guide wire and/or inner mandrel, at least one retaining wire, and an extraction wire; wherein a retaining wire loop is formed as taught by Shaw et al.

The suggestion/motivation for doing so would have been to facilitate and enhance the ease of delivering/retracting the implantable device (Shaw et al, Col. 3, lines 23-55)

Therefore, it would have been obvious to combine Shaw et al with Amplatz et al to obtain the invention as specified in the instant claims.

14. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Shaw et al (US Pat. No.: 6,171,329) as applied to claim 67 above, and further in view of Thill et al (US Pat. No.: 6,124,029).

In regard to claim 69, Amplatz et al in view of Shaw et al discloses all the limitations of the claim but fails to disclose an extraction wire (46) in a loop or hoop and threaded through at least one hoop or loop at one end of said proximal or distal portions of the support structure (Fig. 1). However, Thill et al discloses an extraction wire in a loop or hoop and threaded through at least one hoop or loop at one end of said proximal portion of the support structure.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Amplatz et al in view of Shaw et al to include extraction wire in a loop or hoop and threaded through at least one hoop or loop at one end of said proximal portion of the support structure as taught by Thill et al.

The suggestion/motivation for doing so would have been to aid in the collapse of the support structure during reversible retrieval of the device into the catheter (Thill et al, Col. 6, lines 17-23).

Therefore, it would have been obvious to combine Thill et al with Amplatz et al and Shaw et al to obtain the invention as specified in the instant claims.

Response to Arguments

15. Applicant's arguments with respect to claims 40-50, 52-63 and 65-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, UYEN (JACKIE) HO can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./

Examiner, Art Unit 3773

11/15/2010

/Darwin P. Erezon/

Primary Examiner, Art Unit 3773